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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09-802,162	03/08/2001	Robert Getts	4081 005	6213

7590

03/24/2003

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 03/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/802,162

Applicant(s)

GETTS, ROBERT

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' response to the office action and amendment (Paper No. 6) filed on December 26, 2002 has been entered.
2. Applicants' amendment and response to the previous office action states (page 1 of the amendment) that new claims 20-24 are added. However, Examiner notes that the amendment does not comprise new claims 20-24.

Response to Arguments

3. Applicant's response to the office action (Paper No.6) is fully considered and found persuasive in part in view of amendment and arguments.
4. With reference to the objection made in the previous office action, to the abstract of the instant specification, the objection is withdrawn herein, in view of Applicants' amendment (Paper No.14).
5. With reference to the rejection made in the previous office action under 35 USC 112 second paragraph, applicants' arguments and amendment have been fully considered and the rejection is withdrawn herein.
6. With reference to the rejection in the previous office action under 35 U.S.C. 102(b), applicants' arguments and amendment have been fully considered and the rejection and the rejection is withdrawn in view of the arguments.
7. With reference to the rejection in the previous office action under 35 U.S.C. 103(a), applicants' arguments and amendment have been fully considered and the rejection is moot in view of the amendment and new grounds of rejection.

New Grounds of Rejections

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. Claims 1 and 18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 09/908,950 ('950). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims teach a method for detection and assay on a microarray comprising (a) contacting first component (cDNA having a capture sequence) and second component (having dendrimer having a label) simultaneously or in a pre-hybridized form with a microarray having plurality of features each containing a particular nucleotide sequence (b) incubating the mixture at a time sufficient to enable the first nucleotide sequence of the said microarray bind to the first component, resulting in a hybridization pattern. The claims in the co-pending application ('950) encompass the instant method limitations and obvious over the claims in the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

B. Claims 1 and 18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, and 5 of copending Application No. 10/050,088 ('088). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims teach a method for detection and assay on a microarray comprising (a) contacting first component (cDNA having a capture sequence) and second component (having dendrimer having a label) simultaneously or in a pre-hybridized form with a microarray having plurality of features each containing a particular nucleotide sequence (b) incubating the mixture at a time sufficient to enable the first nucleotide sequence of the said microarray bind to the first component, resulting in a hybridization pattern. The claims in the co-pending application ('088) encompass the instant method limitations and obvious over the claims in the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schena et al. (Science, Vol. 270, pp. 467-470, 1995) and in view of Nilsen et al. (USPN. 5,487,973).

Schena et al. teaches a method for quantitative gene expression with a cDNA microarray (see page 467, summary, page 469, column 3, paragraph 1) wherein Schena et al. teaches (1)

incubating a cDNA array with a first component comprising cDNA having a fluorescent label obtained from mRNA (see page 467, column 3, paragraph 2, page 470, column 1, ref. 5); (2) mixing said first component with said microarray at a temperature and for a time sufficient to enable the nucleotide sequence on the microarray binds to the first component resulting in the generation of a hybridization pattern on the microarray (see page 467, column 3, paragraph 2, page 470, column 1, ref. 6) Schena et al. also teach (i) cDNA reagent comprising formed by contacting target sample mRNA with oligo (dT) primer, reverse transcriptase and labeled dNTPs under conditions sufficient for initiating reverse transcription of said mRNA in to cDNA (see page 467, column 3, paragraph 2, page 470, column 1, ref 5); (ii) hybridization wash solutions including varying concentrations of SSC (1- 0.1X) and SDS (0.1%), hybridization conditions including hybridization temperatures ranging from 25⁰ - 65⁰ C in a hybridization chamber (see page 467, column 3, paragraph 2); incubating the said mixture for 18 hours to enable the binding of said first component with the particular nucleotide sequence on the said microarray (see page 467, column 3, paragraph 2, page 470, column 1, ref. 6). However, Schena et al. did not teach a second component comprising a dendrimer having at least one arm comprising a label and at least another arm having a second nucleotide sequence complementary to a capture sequence present on the first component.

Nilsen et al. teach a method for detecting a specific nucleic acid in a target sample wherein Nilsen et al. teach that the method comprises (i) contacting a bead having specific probe sequences with a mixture containing a first component comprising labeled target nucleic acid (DNA or RNA) having a capture sequence and a second component comprising a dendrimer having at least one arm with a nucleotide sequence complementary to the capture sequence of the

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first component (see column 14, lines 30-35, column 15, lines 37-63); (ii) mixing the first and second components at a temperature to form a bridge between the two components to enable the cross-linking of first component to the second (see column 16, lines 8-11); and incubating the bound mixture with the said bead and detecting signal as an indication of the binding of the target sequence to the specific probe sequence on the bead (see column 16, lines 12-67, column 18, lines 27-51). Nilsen et al. also teach that the method comprises annealing times ranging from 8minutes (see column 20, lines 24-44) to overnight to 2-6 weeks (see column 3, lines 49-60); detection of hybridization pattern includes detecting the detectable signal (see column 20, lines 38-40); the method comprises hybridization buffer (see column 19, lines 14-26); the unbound dendrimers were removed by a washing step (see column20, lines 35-37); and the isolation of nucleic acid includes spin column (see column20, lines 17-19). However, Nilsen et al. did not teach end-labeling or attaching capture sequence to the target sample.

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made, to modify a method for quantitative gene expression using cDNA microarray and hybridization as taught by Schena et al. with a method for detecting a nucleic acid sequence using dendrimer as taught by Nilsen et al. to achieve expected advantage of developing an enhanced sensitivity of detecting a target nucleic acid because Nilsen et al. states that "background noise could be generated in conventional assay not only from binding to a solid support, but also from binding of the probe to nonhomologous DNA sequences. An open branching of a dendrimeric DNA have many degrees of freedom in their movement relative to each other and have a high avidity for DNA that is complementary to the non-annealed single stranded sequences (see column 18, lines 14-26, column 7, lines 14-19). An ordinary practitioner

would have been motivated to combine the method of Schena et al. with the method of Nilsen et al. in order to achieve the expected advantage of developing a sensitive method for detecting a target nucleic acid because the addition of the limitation as taught by Nilsen et al. would reduce non-specific binding and reduce background noise in hybridization assays.

Further selection of specific hybridization buffers, hybridization conditions and automation of hybridization assay represents routine optimization with regard to hybridization, which routine optimization parameters are explicitly recognized in Schena et al. As noted in *In re Aller*, 105 USPQ 233 at 235, more particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to cover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the hybridization buffers or conditions performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-305-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
March 20, 2003


JEFFREY FREDMAN
PRIMARY EXAMINER